various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 19, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. § 180.505, is amended by:
■ i. Revise paragraph (a)(1) introductory text and paragraph (a)(2) introductory text;
■ ii. Add alphabetically an entry for ''Vegetable, cucurbit, group 9'' to the table in paragraph (a)(1).

The added and revised text read as follows:

§ 180.505 Emamectin; tolerances for residues.

(a) *General.* (1) Tolerances are established for emamectin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of emamectin (a mixture of a minimum of 90% 4′-epi-methylamino-4′-deoxyavermectin B_{1a} and maximum of 10% 4′-epi-methylamino-4′-deoxyavermectin B_{1b}) and its metabolites 8,9-isomer of the B_{1a} and B_{1b} component of the parent (8,9-ZMA), or 4′-deoxy-4′-epi-amino-avermectin B_{1a} and 4'-deoxy-4'-epi-amino-avermectin B_{1b}; 4′-deoxy-4′-epi-amino avermectin B_{1a} (AB_{1a}); 4′-deoxy-4′-epi-(*N*-formyl-*N*-methyl)amino-avermectin (MFB_{1a}); and 4′-deoxy-4′-epi-(*N*-formyl)amino-avermectin B_{1a} (FAB_{1a}), calculated as the stoichiometric equivalent of emamectin.

Commodity	Parts per million
* * * * *	
Vegetable, cucurbit, group 9	0.02
* * * * *	

(2) Tolerances are established for emamectin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of emamectin (MAB_{1a} + MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-$_{1a}$ and 8,9-ZB_{1b}).

* * * * *

[FR Doc. 2013–06758 Filed 3–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0488; FRL–9377–3]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide thiamethoxam in or on tea, and amends the existing tolerance for residues of thiamethoxam in or on coffee. Syngenta Crop Protection, Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 27, 2013. Objections and requests for hearings must be received on or before May 28, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0488, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Julie Chao, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8735; email address: *chao.julie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR Web site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an

objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0488 in the subject line on the first Web page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before May 28, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0488, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 22, 2012 (77 FR 50661) (FRL–9358–9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8036) by Syngenta Crop Protection, Inc.; P.O. Box 18300; Greensboro, NC 27419. The petition requested that 40 CFR 180.565 be amended by increasing the tolerance for residues of the insecticide thiamethoxam, (3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4 H -1,3,5-oxadiazin-4-imine) and its metabolite CGA–322704 [N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine], in or on coffee from 0.05 parts per million (ppm) to 0.2 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

In the **Federal Register** of December 19, 2012 (77 FR 75082) (FRL–9372–6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8011) by Syngenta Crop Protection, Inc.; P.O. Box 18300; Greensboro, NC 27419. The petition requested that 40 CFR 180.565 be amended by establishing a tolerance for residues of the insecticide thiamethoxam, (3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4 H–1,3,5-oxadiazin-4-imine) and its metabolite CGA–322704 [N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N'-nitro-guanidine], in or on tea at 20 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, Inc., the registrant, which is available in the docket, *http://www.regulations.gov.* The notice of filing mistakenly referenced PP 2E8011. The correct petition number is PP 2E8100. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue * * *''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiamethoxam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with thiamethoxam follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Thiamethoxam shows toxicological effects primarily in the liver, kidney, testes, and hematopoietic system. In addition, developmental neurological effects were observed in rats. This developmental effect is being used to assess risks associated with acute exposures to thiamethoxam, and the liver and testicular effects are the basis for assessing longer term exposures. Although thiamethoxam causes liver tumors in mice, the Agency has classified thiamethoxam as ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently in the mouse. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer.

Specific information on the studies received and the nature of the adverse effects caused by thiamethoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in Section 4.5.1 of the documents ''Thiamethoxam. Human Health Risk Assessment for the Higher Tolerance, Use of New Formulations, and Increased Maximum Seasonal Application Rate on Imported Coffee Beans, and Condition-of-Registration Data for Leafy Vegetables (Group 4),'' in docket ID number EPA–HQ–OPP–2012–0488, and ''Thiamethoxam. Human Health Risk Assessment for Residues on

Imported Tea Leaves (Dried),'' in docket ID number EPA–HQ–OPP–2012–0858.

Thiamethoxam produces a metabolite known as CGA–322704 (referred to in the remainder of this rule as clothianidin). Clothianidin is also registered as a pesticide. While some of the toxic effects observed following testing with thiamethoxam and clothianidin are similar, the available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately. A separate risk assessment of clothianidin, which takes into account contributions from thiamethoxam, has been completed in conjunction with the registration of clothianidin. The most recent assessment, which provides details regarding the toxicology of clothianidin, is available in the docket EPA–HQ–OPP–2011–0860, at *http://www.regulations.gov.* Refer to the document ''Clothianidin—Aggregate Human Health Risk Assessment of New Uses on Strawberry, Pistachio, and Citrus; New Tolerance for Tea; and Revised PHI and Tolerance for Pepper and Eggplant (Crop Subgroup 8–10B).''

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for thiamethoxam used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of March 2, 2012 (77 FR 12731) (FRL–9331–8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing thiamethoxam tolerances in 40 CFR 180.565. EPA assessed dietary exposures from thiamethoxam in food as follows:

For both acute and chronic exposure assessments for thiamethoxam, EPA combined residues of clothianidin coming from thiamethoxam with residues of thiamethoxam *per se.* As discussed in the previous unit, thiamethoxam's major metabolite is CGA–322704, which is also the registered active ingredient clothianidin. Available information indicates that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately; however, these exposure assessments for this action incorporated the total residue of thiamethoxam and clothianidin from use of thiamethoxam because the total residue for each commodity for which thiamethoxam has a tolerance has not been separated between thiamethoxam and its clothianidin metabolite. The combining of these residues, as was done in this assessment, results in highly conservative estimates of dietary exposure and risk.

A separate assessment was done for clothianidin. The clothianidin assessment included clothianidin residues from use of clothianidin as a pesticide or clothianidin residues from use of thiamethoxam on those commodities for which the pesticide clothianidin does not have a tolerance. The two sources of clothianidin were not combined for a given commodity because (1) residues of clothianidin are greater from clothianidin use than from thiamethoxam use; and (2) it was assumed that 100% of crops are treated.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for thiamethoxam. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues of thiamethoxam and clothianidin. It was further assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level and/or anticipated residues (averages) from field trial data. It was again assumed that 100% of crops with registered or requested uses of thiamethoxam and 100% of crops with registered or requested uses of clothianidin were treated. A complete listing of the inputs used in these assessments can be found in the following documents: ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Use of Thiamethoxam on Imported Coffee Beans and Condition-of-Registration Residue Data for Leaf Lettuce,'' available in the docket EPA–HQ–OPP–2012–0488; ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Residues of Thiamethoxam on Imported Tea,'' available in the docket EPA–HQ–OPP–2012–0858; and ''Clothianidin—Aggregate Human Health Risk Assessment of New Uses on Strawberry, Pistachio, and Citrus; New Tolerance for Tea; and Revised PHI and Tolerance for Pepper and Eggplant (Crop Subgroup 8–10B),'' available in the docket EPA–HQ–OPP–2011–0860, at *http://www.regulations.gov.*

iii. *Cancer.* EPA concluded that thiamethoxam is ''not likely to be carcinogenic to humans'' based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse, and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently in the mouse. The non-cancer (chronic) assessment is sufficiently protective of the key events (perturbation of liver metabolism, hepatotoxicity/regenerative proliferation) in the animal mode of action for cancer and thus a separate exposure assessment pertaining to

cancer risk is not necessary. Because clothianidin is not expected to pose a cancer risk, a quantitative dietary exposure assessment for the purposes of assessing cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Tolerance level residues or anticipated residues (average) from the field trial data were used for the chronic assessment for thiamethoxam. It was assumed that 100% of crops were treated for all food commodities in both the acute and chronic analyses.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for thiamethoxam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of thiamethoxam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Tier 1 Rice Model for surface water and the Screening Concentration in Ground Water (SCI–GROW) model for ground water, the estimated drinking water concentrations (EDWCs) of thiamethoxam for acute exposures are estimated to be 0.13177 ppm for surface water and 0.00466 ppm for ground water. The chronic concentrations for surface water and ground water are estimated to be 0.01131 ppm and 0.00466 ppm, respectively. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. Since clothianidin is not a significant degradate of thiamethoxam in surface water or ground water sources of drinking water, it was not included in the EDWCs for the thiamethoxam dietary assessment. For the clothianidin assessments, the EDWC value of 0.072 ppm for clothianidin was incorporated into the acute and chronic dietary assessments. A complete listing of the inputs used in these assessments can be found in the following documents: ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Use of Thiamethoxam on Imported Coffee Beans and Condition-of-Registration Residue Data for Leaf Lettuce,'' available in the docket EPA–HQ–OPP–2012–0488; ''Thiamethoxam. Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for Residues of Thiamethoxam on Imported Tea,'' available in the docket EPA–HQ–OPP–2012–0858; and ''Clothianidin— Aggregate Human Health Risk Assessment of New Uses on Strawberry, Pistachio, and Citrus; New Tolerance for Tea; and Revised PHI and Tolerance for Pepper and Eggplant (Crop Subgroup 8–10B),'' available in the docket EPA–HQ–OPP–2011–0860, at *http://www.regulations.gov.*

The registrant has conducted small-scale prospective ground water studies in several locations in the United States to investigate the mobility of thiamethoxam in a vulnerable hydrogeological setting. A review of those data show that generally, residues of thiamethoxam, as well as clothianidin, are below the limit of quantification (0.05 ppb). When quantifiable residues are found, they are sporadic and at low levels. The maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for clothianidin. These values are well below the modeled estimates summarized in this unit, indicating that the modeled estimates are, in fact, protective of what actual exposures are likely to be.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Thiamethoxam is currently registered for the following uses that could result in residential exposures: Turfgrass on golf courses, residential lawns, commercial grounds, parks, playgrounds, athletic fields, landscapes, interiorscapes, sod farms, and indoor crack and crevice or spot treatments to control insects in residential settings. EPA assessed residential exposures for those making applications in residential settings as well as for those entering areas previously treated with thiamethoxam. Exposures are expected to be short-term (i.e., up to 30 days) in duration.

Adults were assessed for potential short-term dermal and inhalation handler exposure from applying thiamethoxam to turf/lawns and from indoor crack and crevice/spot treatment applications. Short-term postapplication exposures (1 to 30 days of continuous exposure) may also occur as a result of activities on treated turf or entering indoor areas previously treated with a thiamethoxam indoor crack and crevice product. EPA combined non-dietary routes of children's post application exposure to obtain an estimate of potential combined exposure. These scenarios consisted of dermal postapplication exposure and oral (hand-to-mouth) exposures for children 1 to < 2 years of age. A complete listing of the inputs used in these assessments can be found in the document ''Thiamethoxam: Revised Residential Exposure Assessment to Support an Amended Import Tolerance for Coffee,'' in docket ID number EPA–HQ–OPP–2012–0488 at *http://www.regulations.gov.*

Clothianidin is currently registered for the following uses that could result in residential exposures: turf, ornamental plants, and/or indoor use to control bed bugs. EPA assessed residential exposure using the following assumptions: exposures may occur during application of products containing clothianidin (handler exposure) as well as following application (post-application exposure) and are expected to be of short-term (1–30 days) duration.

Adults were assessed for potential short-term dermal and inhalation handler exposure from applying clothianidin to residential turf/home lawns and for short-term post-application dermal exposure from contact with treated residential and recreational turf home lawns and golf courses. There is also potential for post-application dermal and inhalation exposure for adults and children resulting from use of clothianidin on residential turf, ornamentals (i.e., trees), and indoor use to control bed bugs. There is also potential for incidental oral post-application exposure for children. Although there is potential for adult exposure resulting from both applying the product and post application activities, the Agency did not combine exposure estimates from adult handler and post application activities because of the conservative assumptions and inputs within each exposure scenario. The children's

combined exposure includes only the hand-to-mouth exposure for the incidental oral exposure component. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth would overestimate incidental oral exposures for purposes of estimating combined residential exposure. Further, because the level of concern for dermal exposures (MOEs less than 100) and inhalation exposure (MOEs less than 1000) are different, a total aggregate risk index (ARI) approach was used instead of the MOE approach. ARIs of greater than 1 indicate risks are not of concern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Thiamethoxam is a member of the neonicotinoid class of pesticides and produces, as a metabolite, another neonicotinoid, clothianidin. Structural similarities or common effects do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same sequence of major biochemical events. Although clothianidin and thiamethoxam bind selectively to insect nicotinic acetylcholine receptors (nAChR), the specific binding site(s)/receptor(s) for clothianidin, thiamethoxam, and the other neonicotinoids are unknown at this time. Additionally, the commonality of the binding activity itself is uncertain, as preliminary evidence suggests that clothianidin operates by direct competitive inhibition, while thiamethoxam is a non-competitive inhibitor. Furthermore, even if future research shows that neonicotinoids share a common binding activity to a specific site on insect nicotinic acetylcholine receptors, there is not necessarily a relationship between this pesticidal action and a mechanism of toxicity in mammals. Structural variations between the insect and mammalian nAChRs produce quantitative differences in the binding affinity of the neonicotinoids towards these receptors, which, in turn, confers the notably greater selective toxicity of this class towards insects, including aphids and leafhoppers, compared to mammals. While the insecticidal action of the neonicotinoids is neurotoxic, the most sensitive regulatory endpoint for thiamethoxam is based on unrelated effects in mammals, including effects on the liver, kidney, testes, and hematopoietic system. Additionally, the most sensitive toxicological effect in mammals differs across the neonicotinoids (e.g., testicular tubular atrophy with thiamethoxam; mineralized particles in thyroid colloid with imidacloprid). Thus, EPA has not found thiamethoxam or clothianidin to share a common mechanism of toxicity with any other substances. For the purposes of this tolerance action, therefore, EPA has assumed that thiamethoxam and clothianidin do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* In the developmental studies, there is no evidence of increased quantitative or qualitative susceptibility of rat or rabbit fetuses to *in utero* exposure to thiamethoxam. The developmental NOAELs are either higher than or equal to the maternal NOAELs. The toxicological effects in fetuses do not appear to be any more severe than those in the dams or does. In the rat developmental neurotoxicity study, there was no quantitative evidence of increased susceptibility; however, there was increased qualitative susceptibility because the effects in the pups (reduced brain weight and significant changes in brain morphometric measurements) were considered to be more severe than findings in the dams (decreased body weight gain and food consumption). There is evidence of increased quantitative susceptibility for male pups in both 2-generation reproductive studies. In one study, there are no toxicological effects in the dams; whereas, for the pups, reduced bodyweights are observed at the highest dose level, starting on day 14 of lactation. This contributes to an overall decrease in bodyweight gain during the entire lactation period. The reproductive effects in males appear in the F_1 generation in the form of increased incidence and severity of testicular tubular atrophy. These data are considered to be evidence of increased quantitative susceptibility for male pups (increased incidence of testicular tubular atrophy at 1.8 milligrams/kilogram/day (mg/kg/day) when compared to the parents (hyaline changes in renal tubules at 61 mg/kg/day; NOAEL is 1.8 mg/kg/day). In a more recent 2-generation reproduction study, the most sensitive effect was sperm abnormalities at 3 mg/kg/day (the NOAEL is 1.2 mg/kg/day) in the F_1 males. This study also indicates increased susceptibility for the offspring for this effect. Although there is evidence of increased quantitative susceptibility for male pups in both reproductive studies, NOAELs and LOAELs were established in these studies and the Agency selected the NOAEL for testicular effects in F_1 pups as the basis for risk assessment. The Agency has confidence that the NOAEL selected for risk assessment is protective of the most sensitive effect (testicular) for the most sensitive subgroup (pups) observed in the toxicological database.

3. *Conclusion.* i. In the final rule published in the **Federal Register** of January 5, 2005 (70 FR 708) (FRL–7689–7), EPA had previously determined that the FQPA SF should be retained at 10X for thiamethoxam, based on the following factors: Effects on endocrine organs observed across species; significant decrease in alanine amino transferase levels in companion animal studies and in dog studies; the mode of action of this chemical in insects (interferes with the nicotinic acetylcholine receptors of the insect's nervous system); the transient clinical signs of neurotoxicity in several studies across species; and the suggestive evidence of increased quantitative susceptibility in the rat reproduction study. Since that determination, EPA has received and reviewed a developmental neurotoxicity (DNT) study in rats, and an additional reproduction study in rats. Taking the

results of these studies into account, as well as the rest of the data on thiamethoxam, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X (June 23, 2010, 75 FR 35653; FRL–8830–4); (June 22, 2007, 72 FR 34401). That decision is based on the following findings:

a. The toxicity database for thiamethoxam is largely complete, including acceptable/guideline developmental toxicity, 2-generation reproduction, DNT, and immunotoxicity studies. The available data for thiamethoxam show the potential for immunotoxic effects. In the subchronic dog study, leukopenia (decreased white blood cells) was observed in females only, at the highest dose tested (HDT) of 50 mg/kg/day; the NOAEL for this effect was 34 mg/kg/day. The overall study NOAEL was 9.3 mg/kg/day in females (8.2 mg/kg/day in males) based on hematology and other clinical chemistry findings at the LOAEL of 34 mg/kg/day (32 mg/kg/day in males). In the subchronic mouse study, decreased spleen weights were observed in females at 626 mg/kg/day; the NOAEL for this effect was the next lowest dose of 231 mg/kg/day. The overall study NOAEL was 1.4 mg/kg/day (males) based on increased hepatocyte hypertrophy observed at the LOAEL of 14.3 mg/kg/day. The decreased absolute spleen weights were considered to be treatment related, but were not statistically significant at 626 mg/kg/day or at the HDT of 1,163 mg/kg/day. Since spleen weights were not decreased relative to body weights, the absolute decreases may have been related to the decreases in body weight gain observed at higher doses. Overall, the Agency has a low concern for the potential for immunotoxicity related to these effects for the following reasons: In general, the Agency does not consider alterations in hematology parameters alone to be a significant indication of potential immunotoxicity. In the case of thiamethoxam, high-dose females in the subchronic dog study had slight microcytic anemia as well as leukopenia characterized by reductions in neutrophils, lymphocytes and monocytes; the leukopenia was considered to be related to the anemic response to exposure. Further, endpoints and doses selected for risk assessment are protective of the observed effects on hematology. Spleen weight decreases, while considered treatment-related, were associated with decreases in body weight gain, and were not statistically significant. In addition, spleen weight changes occurred only at very high doses, more than 70 times higher than the doses selected for risk assessment. In addition to the previous considerations, a 28-day immunotoxicity study in female mice was recently received and has undergone a preliminary review. There were no immunotoxic effects observed at doses exceeding the limit dose of 1,000 mg/kg/day.

b. For the reasons discussed in Unit III.D.2., there is low concern for an increased susceptibility in the young.

c. Although there is evidence of neurotoxicity after acute exposure to thiamethoxam at doses of 500 mg/kg/day including drooped palpebral closure, decrease in rectal temperature and locomotor activity and increase in forelimb grip strength, no evidence of neuropathology was observed. These effects occurred at doses at least 14-fold and 416-fold higher than the doses used for the acute, and chronic risk assessments, respectively; thus, there is low concern for these effects since it is expected that the doses used for regulatory purposes would be protective of the effects noted at much higher doses. In the developmental neurotoxicity study (DNT), there was no evidence of neurotoxicity in the dams exposed up to 298.7 mg/kg/day; a dose that was associated with decreases in body weight gain and food consumption. In pups exposed to 298.7 mg/kg/day, there were significant reductions in absolute brain weight and size (i.e., length and width of the cerebellum was less in males on day 12, and there were significant decreases in Level 3–5 measurements in males and in Level 4–5 measurements in females on day 63). However, there is low concern for this increased qualitative susceptibility observed in the DNT study because the doses and endpoints selected for risk assessment are protective of the effects in the offspring. As noted previously, for risk assessment the Agency selected the NOAEL for testicular effects in F_1 pups based on two reproductive toxicity studies to be protective of all sensitive subpopulations.

d. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed using tolerance-level and/or anticipated residues that are based on reliable field trial data observed in the thiamethoxam field trials. Although there is available information indicating that thiamethoxam and clothianidin have different toxicological effects in mammals and should be assessed separately, the residues of each have been combined in these assessments to ensure that the estimated exposures of thiamethoxam do not underestimate actual potential thiamethoxam exposures. An assumption of 100 percent crop treated (PCT) was made for all foods evaluated in the assessments. For the acute and chronic assessments, the EDWCs of 131.77 parts per billion (ppb) and 11.3 ppb, respectively, were used to estimate exposure via drinking water. Compared to the results from small scale prospective ground water studies where the maximum observed residue levels from any monitoring well were 1.0 ppb for thiamethoxam and 0.73 ppb for clothianidin, the modeled estimates are protective of what actual exposures are likely to be. EPA used similarly conservative (protective) assumptions to assess postapplication exposure to children and adults including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by thiamethoxam.

ii. In the final rule published in the **Federal Register** of February 6, 2008 (73 FR 6851) (FRL–8346–9), EPA had previously determined that the FQPA SF for clothianidin should be retained at 10X because EPA had required the submission of a developmental immunotoxicity study to address the combination of evidence of decreased absolute and adjusted organ weights of the thymus and spleen in multiple studies in the clothianidin database, and evidence showing that juvenile rats in the 2-generation reproduction study appear to be more susceptible to these potential immunotoxic effects. In the absence of a developmental immunotoxicity study, EPA concluded that there was sufficient uncertainty regarding immunotoxic effects in the young that the 10X FQPA factor should be retained as a database uncertainty factor. Since that determination, EPA has received and reviewed an acceptable/guideline developmental immunotoxicity study, which demonstrated no treatment-related effects. Taking the results of this study into account, as well as the rest of the data on clothianidin, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF for clothianidin were reduced to 1X (February 11, 2011, 76 FR 7712) (FRL–8858–3). That decision is based on the following findings:

a. The toxicity database for clothianidin is complete. As noted, the prior data gap concerning developmental immunotoxicity has been addressed by the submission of an

acceptable developmental immunotoxicity study.

b. A rat developmental neurotoxicity study is available and shows evidence of increased quantitative susceptibility of offspring. However, EPA considers the degree of concern for the developmental neurotoxicity study to be low for prenatal and postnatal toxicity because the NOAEL and LOAEL were well characterized, and the doses and endpoints selected for risk assessment are protective of the observed susceptibility; therefore, there are no residual concerns regarding effects in the young.

c. While the rat multi-generation reproduction study showed evidence of increased quantitative susceptibility of offspring compared to adults, the degree of concern is low because the study NOAEL and LOAEL have been selected for risk assessment purposes for relevant exposure routes and durations. In addition, the potential immunotoxic effects observed in the study have been further characterized with the submission of a developmental immunotoxicity study that showed no evidence of susceptibility. As a result, there are no concerns or residual uncertainties for prenatal and postnatal toxicity after establishing toxicity endpoints and traditional UFs to be used in the risk assessment for clothianidin.

d. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on assumptions that were judged to be highly conservative and health-protective for all durations and population subgroups, including tolerance-level residues, adjustment factors from metabolite data, empirical processing factors, and 100 PCT for all commodities. Additionally, EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to clothianidin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children and adults as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by clothianidin.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to thiamethoxam will occupy 9.5% of its aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Acute dietary exposure from food and water to clothianidin is estimated to occupy 28% of its aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* In examining chronic aggregate risk, EPA has assumed that the only pathway of exposure relevant to that time frame is dietary exposure. Using this assumption for chronic exposure, EPA has concluded that chronic exposure to thiamethoxam from food and water will utilize 45% of its cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic exposure to clothianidin from food and water will utilize 28% of its cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiamethoxam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to thiamethoxam. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures for thiamethoxam result in aggregate MOEs of 430 for adults and 450 for children 1 to 2 years. Because EPA's level of concern for thiamethoxam is a MOE of 100 or below, these MOEs are not of concern.

For the clothianidin aggregate assessment, the EPA selected the worst-case adult and children exposure scenarios. The treatment of tree trunks using a manually-pressurized hand wand presents the worst-case exposure estimate for adults, while the bed bug scenario presents the worst-case exposure estimates for children 1 to < 2 years old. For short- and intermediate-term ''worst-case'' aggregate exposure estimates, the ARI for adults is 6.5 and for children 1 to < 2 years old, the ARI is estimated at 1.2. ARI estimated values greater than 1.0 indicate risks are not of concern.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, intermediate term exposures (30 to 180 days of continuous exposure) are not expected from the registered turf and/or indoor uses of thiamethoxam. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for thiamethoxam.

For purposes of performing a clothianidin aggregate assessment, the EPA selected the worst-case adult and children exposure scenarios. The treatment of tree trunks using a manually-pressurized hand wand presents the worst-case exposure estimate for adults, while the bed bug scenario presents the worst-case exposure estimates for children 1 to < 2 years old. For short- and intermediate-term ''worst-case'' aggregate exposure estimates, the ARI for adults is 6.5 and for children 1 to <2 years old, the ARI is estimated at 1.2. ARI estimated values greater than 1.0 indicate risks are not of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has classified thiamethoxam as not likely to be a human carcinogen based on convincing evidence that a non-genotoxic mode of action for liver tumors was established in the mouse and that the carcinogenic effects are a result of a mode of action dependent on sufficient amounts of a hepatotoxic metabolite produced persistently. Therefore, thiamethoxam is not expected to pose a cancer risk. Clothianidin has been classified as ''not likely to be a human carcinogen'' and is not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to thiamethoxam or clothianidin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Production Liquid Chromatography (HPLC) Method AG–675 with ultraviolet (UV) or Mass Spectrometry (MS) detection) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for thiamethoxam in or on coffee at 0.2 ppm, and tea at 20 ppm. These MRLs are the same as the tolerances established for thiamethoxam in the United States.

V. Conclusion

Therefore, tolerances are established for residues of thiamethoxam, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine and its metabolite CGA–322704 N-[(2-chloro-thiazol-5-yl)methyl]-N′-methyl-N″-nitro-guanidine, calculated as the stoichiometric equivalent of thiamethoxam, in or on coffee, green, bean at 0.20 ppm and tea, dried at 20 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 15, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.565, in the table in paragraph (a), remove the entry for ''Coffee, bean, green[1],'' and footnote 1, and add alphabetically entries for ''coffee, green, bean[1]'' new footnote 1, and ''tea, dried,'' to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Coffee, green, bean[1]	0.20
* * * * *	
Tea, dried[1]	20
* * * * *	

[1] There are no U.S. registrations as of March 27, 2013.

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